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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	**PAPER NUMBER**
3738	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/720,656	FREY ET AL.	
	Examiner	Art Unit	
	Ann Schillinger	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48 and 57-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28,32-48 and 57-64* is/are rejected.

7)☒ Claim(s) *29-31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Attachment A*.

DETAILED ACTION

Claim Objections

Claims 29-31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by McCrory (U.S. Pat. No.: 1400616). McCrory discloses a frame with portions lining in a first and second plane, where the planes form an angle (Figure 1) where the angle is ~30° as shown in the drawing below. A number of retractors are attached to the frame where there are 4 retractors, each retractor has a parallel opposing counterpart and extend transversely to a plane where the members are fully capable of encircling an opening and form an oval shape on the frame. The device is fully capable of being positioned along the spine where a portion will lie posterior and/or posterior-lateral and along the mid-line of the spine. With regards to the amendment of claim 1, McCrory discloses the following: said first and second portions of said frame each include a recess (portions of the frame where screws go through) to receive clamping devices coupled to respective ones of said retractors about said frame with said clamping devices being slideable (screws can move in and out) from said respective recess along a respective one of said

first and second portions of said frame for attachment to said respective portion of said frame at a selected position therealong spaced from said recess (shown in Figure 1).

Claims 41, 44, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Kluger (DE 8704901 U). Kluger discloses first and second anchors (19) and a frame (2) lying in at least one plane where first (4) and second (2) distractor mechanisms are attachable to the frame and extend transversely and are engagable to the anchors where portion 3 includes a locking wheel mechanism to fixedly secure the device and the device includes the pivoting portions 5 and 5a, allowing for a pivotal relationship with the anchors where the anchors are multi axial screws as demonstrated by the circular rotation aspect (32) of Figures 5 and 6). With regards to the amendments of claim 41, Kluger discloses said first and second distractor mechanisms adjacent a proximal end of said respective distractor mechanism as shown in Figure 1; and the proximal ends of said distractor mechanisms (30, 31) to pivot relative to said adjustment mechanism (22, 23) about said distal ends thereof toward and away from said frame (col. 3, lines 29, 36).

Claims 57-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Mayer et al. (U.S. Pat No. 5728046). Mayer et al. discloses the following regarding claim 57: a surgical instrumentation system to provide a surgical approach to a patient's spine, comprising: first and second anchors engagable to first and second vertebrae of the spine (36); a frame lying in at least one plane (Figure 1); a retractor (32) attachable to said frame, said retractor including a blade portion (col. 3, lines 32-36) extending transversely to said at least one plane, said blade portion including a tissue contacting surface (34) adapted to contact and retract tissue from the surgical

approach; a first distractor mechanism (30) attachable to said frame and extending transversely to said at least one plane (Figure 1), said first distractor mechanism including a distal end engageable to said first anchor (32) with said first distractor mechanism in pivotal relation to the first vertebra when said first anchor is engaged with the first vertebra (the screw that is attached to the distractor mechanism will move into the vertebra); a second distractor mechanism (31) attachable to said frame and extending transversely to said at least one plane (Figure 1), said second distractor mechanism including a distal end engageable to said second anchor (32) with said second distractor mechanism in pivotal relation to the second vertebra when said second anchor is engaged with the second vertebra, wherein said first and second distractor mechanisms are each attachable to said frame to fix said first and second distractor mechanisms in position relative to the first and second vertebrae, respectively (as shown in Figure 1, the mechanisms can pivot relative to the frames); first and second adjustment mechanisms (see Attachment A) coupled to respective ones of said first and second distractor mechanisms (Figure 1), said adjustment mechanisms each including a first condition in locking engagement with said respective distractor mechanism to fixedly secure said distractor mechanism relative to said frame and the respective one of the first and second vertebrae, said adjustment mechanisms further each including a second condition in pivotal engagement with said respective distractor mechanism to permit said distractor mechanism to pivot relative to said frame (col. 3, lines 11-29), wherein said adjustment mechanisms each include: an adjustment handle (24, 25); a shaft assembly extending from said adjustment handle, said shaft assembly including an outer shaft and an inner shaft movably positioned within said outer shaft (Attachment A); and an engagement member (22 or 23) at an end of said shaft assembly opposite said adjustment handle,

said engagement member extending from a distal end of said inner shaft and including a number of teeth (threads of the screws) configured to selectively interdigitate and lockingly engage (Figure 1) a number of teeth provided adjacent a proximal end of said distractor mechanism, said number of teeth engaging one another along concave-convex pivot path of said distractor mechanism (threads of screw and teeth along the frame), wherein said adjustment handle is linked with said inner shaft (connected via the screws), said adjustment handle being rotatable to move said inner shaft and said engagement member between said first condition and said second condition (col. 3, lines 21-29).

Mayer et al. discloses the following regarding claim 58: a surgical instrumentation system to provide a surgical approach to a patient's spine, comprising: first and second anchors engageable to first and second vertebrae of the spine (36); a frame lying in at least one plane (Figure 1); a retractor (32) attachable to said frame, said retractor including a blade portion (col. 3, lines 32-36) extending transversely to said at least one plane, said blade portion including a tissue contacting surface (34) adapted to contact and retract tissue from the surgical approach; a first distractor mechanism (30) attachable to said frame and extending transversely to said at least one plane (Figure 1), said first distractor mechanism including a distal end engageable to said first anchor (36) with said first distractor mechanism in pivotal relation to the first vertebra when said first anchor is engaged with the first vertebra (the screw is attached to the distractor mechanism will move into the vertebrae); a second distractor mechanism (31) attachable to said frame and extending transversely to said at least one plane (Figure 1), said second distractor mechanism including a distal end engageable to said second anchor (36) with said second distractor mechanism in pivotal relation to the second vertebra when said second anchor is

engaged with the second vertebra, wherein said first and second distractor mechanisms are each attachable to said frame to fix said first and second distractor mechanisms in position relative to the first and second vertebrae, respectively (as shown in Figure 1, the mechanisms can pivot relative to the frames); first and second adjustment mechanisms (Attachment A) coupled to respective ones of said first and second distractor mechanisms (Figure 1), said adjustment mechanisms each including a first condition in locking engagement with said respective distractor mechanism to fixedly secure said distractor mechanism relative to said frame and the respective one of the first and second vertebrae, said adjustment mechanisms further each including a second condition in pivotal engagement with said respective distractor mechanism to permit said distractor mechanism to pivot relative to said frame (col. 3, lines 11-29), wherein said adjustment mechanisms each include: an engagement member (22 or 23) at a distal end thereof including a number of teeth configured to selectively interdigitate and lockingly engage a number of teeth (threads of the screw) provided adjacent a proximal end of said distractor mechanism (Figure 1), said number of teeth engaging one another along concave-convex pivot path of said distractor mechanism (threads of the screw and the teeth on the frame); and a pair of plates (32) at said distal end of said adjustment mechanism and said distractor mechanism includes a pair of proximal flanges (39, 40) pivotally coupled to said pair of plates (Figure 1).

Mayer et al. discloses the following regarding claim 59: the system of claim 58, wherein: said pair of proximal flanges each include an arcuate slot (29) defining a pivot path of said distractor mechanism; said engagement member includes a slot extending along a longitudinal axis (Figure 1); and said adjustment mechanism further comprises a roller pin (39) coupled

between said pair of plates and extending through 8aid slot of said engagement member and said arcuate slots of said pair of flanges of said distractor mechanism (Figure 1).

Mayer et al. discloses the following regarding claim 60: the system of claim 58, further comprising a second retractor attachable to said frame opposite said retractor (left and right sides).

Mayer et al. discloses the following regarding claim 61: the system of claim 60, wherein said retractor includes a blade portion (col. 3, lines 32-36) defining a substantially fiat tissue contacting surface extending along a longitudinal axis of said blade portion, and said second retractor includes a blade portion defining a concave tissue contacting surface extending along a longitudinal axis of said second retractor (element 34; first and second rectractors on the left and right sides).

The rest of the limitations in claims 62-64 can be seen in Figure 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8-11, 13, 17, 21-27, 32, 33, 36-43, and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCrory (U.S. Pat. No. 1400616) in view of Mayer (U.S. Pa. No. 5728046). McCrory is discussed supra. However, McCrory does not disclose anchors attachable to the vertebrae. Mayer teaches a pair of distractor mechanisms (32) attachable to anchors (36),

which are bone screws where the bone screws are attachable to vertebrae (col. 6, lines 37-47), where the anchors have anchor extensions (35) and the retractor body (32) is about the anchor extensions where the receptacle in the in the retractor (visible in Figure 3) is configured to capture he anchor extension and the distractors are attachable to a frame. Mayer further discloses distractors with locking engagement to fixedly secure (30, 31) where the anchors are fully capable of pivoting relative to the frame, by rotation along the circular path of the securing threaded area (29), additionally the elastic detent device (24, 25) allows for locking in various positions (col. 3, lines 10-20), and are effective releasable clamping devices where Mayer teaches up to 4 of these clamping devices (14,15, 24, 25). The various adjustment mechanisms of Mayer include a handle ((14,15, 24, 25) or (12, 13, 22, 23)) with shaft assembly with engaging threads at the end of the shaft as seen in Figure 1 where the adjustment may occur along teeth. Mayer's teachings are in the same field of endeavor or the analogous art of retractors for the purpose of maintaining an opening during surgery. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of securing members with various adjustment and locking mechanism, as taught by Mayer, to the retractor frame as per McCrory, in order to provide the ability of distraction to the device.

With regards to the amendment of claim 17, Mayer et al. discloses the following: ...and further comprising at least one adjustment mechanism (22 or 23) engaged to at least one of said first and second distractor mechanisms (22, 23 engage with 30, 31) at a pivoting coupling (22, 23) location adjacent a proximal end of said at least distractor mechanism (Figure 1) and a clamping device (24, 25) movable along said frame and operable to clampingly engage said adjustment mechanism to said frame (col. 3, lines 15-20).

With regards to the amendment of claim 22, Mayer et al. discloses the adjustment mechanism as elements 22 or 23.

With regards to the amendment of claim 41, Mayer et al. discloses the following: the first and second adjustment mechanisms coupled to respective ones of said first second distractor mechanisms adjacent a proximal end of said respective distractor mechanism (shown in Figure 1); and proximal ends of said distractor mechanisms (30, 31) to pivot relative to said adjustment mechanism (22, 23) about said distal ends thereof toward and away from said frame (col. 3, lines 29-36).

Claims 12, 14, 18-20, 28, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCrory (U.S. Pat. No. 1400616) in view of Mayer (U.S. Pat. No. 5728046) as disclosed above and further in view of Foley (U.S. Pub. No. 2002/0161368). McCrory and Mayer do not disclose multi-axial fixation screw. Foley teaches multi-axial fixation screws (P 0068) for the purposes of fixation to vertebrae (Figure 21) where the fixation screws contain a yoke (p0068-0071) where the yoke is pivotally attached to a threaded shank and the yoke (68) is an inner cylindrical shaft received in the distal end of an outer shaft (P 0071-0072) that is adapted to fixedly engage the yoke where the inner and outer shaft remain movable relative to one another and the screw remains pivotal. The yoke has two arms as shown in Figure 1, where the arms receive the poly-axial screw as well as portion 90. Foley's teachings are in the same field of endeavor or the analogous art of fixation for the purpose of poly-axially fixedly attaching to the spine. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of poly-axial screws with a yoke, as taught by

Foley, to the retractor-distraction system as per McCrory and Mayer, in order to attach the distraction portion of the device to the spine.

Response to Arguments

Applicant's arguments filed 5/24/2006 have been fully considered but they are not persuasive. Applicant contends that McCrory does not disclose the limitations of the amended claim 1. With regards to claim 1, McCrory discloses the limitations of the amended claim 1 where the screws fit through their respective recesses and are capable of movement relative to the frame. Applicant states that the elements of amended claim 17 are not disclosed by either McCrory or Mayer et al. The elements are disclosed as described above. Applicant's arguments with respect to claim 41 have been considered but are moot in view of the new ground(s) of rejection. As these independent claims are rejected, their dependent claims are rejected as well. For further details, see the rejection as stated above.

Response to Amendment

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn. As the finality of the previous Office action dated on 11/2/2006 is withdrawn, the Examiner has not responded to arguments submitted for that Office action.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger
October 23, 2006

A. Stewart

ALVIN J. STEWART
PRIMARY EXAMINER

Attachment A